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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,449	10/07/2003	Gilbert Theo Hinze	23739-X	3687

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EXAMINER

PAK, JOHN D

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/679,449

Applicant(s)

HINZE, GILBERT THEO

Examiner

JOHN PAK

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5,7-10,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5,7-10,13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/529,734.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 2-5, 7-10 and 13-14 are pending in this application.

Applicant's election with traverse of the invention of Group II in the reply filed on 3/17/2006 is acknowledged. First, applicant's traversal is moot because there is no claim remaining that is directed to the restricted composition invention. Second, even if applicant's argument were relevant to the present fact situation, they would nonetheless be deemed unpersuasive.

Applicant argues that an appropriate explanation as to serious burden has not been established. The Examiner does not agree – see pages 3 and 4 of the Office action of 9/21/2005. Further, electrolytic processing of aqueous solution is an old art, known for example to produce chlorine and purified metals. There are thousands of prior art references that deal with such processes and the composition invention would involve a labor intensive review of all such art to find relevant composition content. Contrary to applicant's unrealistic view of "powerful electronic search engines," composition content and the features involved therein are not efficiently searchable by search engines. Applicant is invited to search in GOOGLE for example, "electrolysis oxidant" and review the more than 56,000 hits and report back whether the search engine argument still holds. Moreover, most non-patent literature is not full-text searchable, so such references, whenever appropriate, must be examined line-by-line in full text the old fashioned way (reading the full document) to determine the composition content. The burden from carrying out such tasks and then additionally

performing a separate and distinct evaluation of the method invention makes the overall burden undue.

Additionally, it must be noted that even the inventor himself believes different uses of the electrolyzed aqueous solution warrants separate patent applications – see separate filings on the same exact date of 4/29/1999 of applications that published as WO 99/20287 (related to instant case) and WO 9920129 (treating animal product, i.e. not live animals).

For these reasons, applicant's traversal of the restriction requirement is deemed unpersuasive and the restriction requirement of record is made FINAL.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-5, 7-10 and 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) Applicant is advised that claim 10 depends on the canceled claim 1. Since the claimed subject matter cannot therefore be determined, claim 10 cannot be further examined on the merits. Claim 10 will not be further treated. If in applicant's next response the subject matter of claim 10 is submitted for examination, a new ground of

rejection will have been necessitated by applicant's amendment, which new ground can be made Final.

(2) The phrase "live animals, and in particular pigs and poultry" recites a genus and a species. The juxtaposition of the species next to the genus raises uncertainties as to the exact scope of live animals, i.e. whether pigs and poultry somehow limits the types of animals. Deleting the species and using a dependent claim to further define live animals is suggested.

(3) Parts of claim 2, reproduced and pointed out below, are indefinite.

altering the chemical composition of the two solutions by
one or more of various hydraulic flow arrangements, linking
electrolytic cell modules in various configurations in order
optimally to address the requirements of specific areas of
application, and manipulating flow rate, hydraulic pressure,
concentration, temperature, current density and/or voltage on
the electrodes;

It is for applicant to set forth what "various hydraulic flow arrangements" are. Same for "various configurations." It is not clear what "in order optimally to address the requirements of specific areas of application" means. What are the "specific areas of application?" What is meant by "optimally?" What parameter is being optimized? What is meant by "manipulating?"

(4) Throughout numerous dependent claims, "the anolyte" and "the catholyte" lack antecedent basis (emphases added). Independent claim 2 does not use the terms anolyte or catholyte.

(5) In claim 3, the "5% and 20%" feature is indefinite because it is unclear what the unit is for the percentages. Is it percent by weight or volume?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 7 appears to contain scientific inaccuracies. In electrolysis cells, the catholyte contains positively charged species and anolyte contains negatively charged species. Claim 7 has it backwards.

It is noted that applicant's specification has conflicting information about this. The disclosure on page 7, first paragraph, is similarly defective as claim 7. The disclosure on page 8, last paragraph, saves the entire specification from being non-

enabling. There, the anolyte is shown (though not stated in explanatory prose) to contain many negatively charged species.

For these reasons of erroneous charged species being attributed to the anolyte and catholyte, claim 7 is not enabled. One skilled in this art would not be able to reverse the natural collection of anionic species to the anode and cationic species to the cathode.

Turning now to prior art based determinations, the Examiner will first set forth the effective filing date of this application. It is noted that this application is a CIP of 09/529,734, which is a 371 of PCT/US98/22372 (filed on 10/23/1998), which claims benefit of a South African application, filed on 10/23/1998. It is also noted that a CIP application claim that does not find support from the parent application or any other earlier application gets its actual filing date as the effective filing date. MPEP 2133.01; see also MPEP 706.02. The following is the difference between the instant application and the earlier filed cases for which applicant claims benefit.

	10/679,449	All earlier filed cases for which benefit is claimed
Is a separated cation containing solution (i.e. catholyte) specifically disclosed to be used to treat a live animal?	Yes, see claim 2.	No. See in <u>WO 99/20287</u> , which is the publication of PCT/US98/22373, page 2, lines 3-4, 8-9 & page 4, lines 12-16: only anion-containing aqueous solution is used to treat; no disclosure of separated catholyte for treatment of live animals. See also page 3, lines 8-10 & claims 1-8.

	10/679,449	All earlier filed cases for which benefit is claimed
Is there any specific disclosure of "altering the chemical composition of the two solutions by one or more of various hydraulic flow arrangements, linking electrolytic cell modules in various configurations ..."? See claim 2	Yes, see claim 2.	No.

Therefore, all the claims here must be given the effective filing date of 10/27/2003. This means that applicant's own WO 99/20287 is now available as prior art against the instant claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-5, 8-9 and 13-14¹ are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/20287 in view of Morrow (US 5,674,537), Shirahata et al. and Kroschwitz et al. (Kirk-Othmer Encyclopedia of Chemical Technology).

WO 99/20287 discloses treatment of pathogenic microorganisms in live animals such as pigs and chickens by administering "electro-chemically activated anion-containing aqueous solution" (page 1, lines 4-13; page 2, lines 1-9; see also claims 1, 3, 7, 8). The electro-chemical reactor may include a through-flow, electrochemical cell having two co-axial cylindrical electrodes with co-axial diaphragm between the electrodes so as to separate the space into catalytic and analytic chamber (page 3, lines 4-7). The anolyte solution contains ozone and anion species such as ClO^- , has a redox potential up to about +600 mv to +800 mv (page 3, lines 14-18), and has a pH of about 6.5 to 7.5 (page 3, last paragraph). The catholyte solution may have a pH of up to about 12-13 and redox potential of about -980 mv (page 4, lines 8-11). Activity against viral organisms and spore and cyst forming bacteria (page 4, lines 1-4). Monitoring of the redox potential of the anolyte during the process is disclosed so that the treatment process may be monitored and controlled (page 4, lines 5-7). Flow rate through the reactor is disclosed to affect efficacy of the anolyte solution (page 8, lines 7-12). Administering the anolyte solution orally by addition to drinking water of

¹ Claim 7 is not included here because said claim is non-enabled. Claim 10 is not included here because it depends on a canceled claim.

piglets/chicklets or by soaking, rinsing, dipping or as an inhalant via an atomizing or fogging (up to 100 micrometer droplets) process is disclosed (page 4, line 12 to page 5, line 4; page 5, lines 11-13). Addition to drinking water is suitable for piglets and chicklets, which are susceptible to stress and accompanying weight loss (sentence bridging pages 4 and 5). Improvement of weight gain is disclosed (page 5, lines 14-16). Anolyte solution diluted to 10% is exemplified (page 7, Experiment 2).

Morrow disclose electrolyzed sodium chloride solution to be used to treat a host animal for a variety of pathogenic diseases (see from column 3, line 28 to column 5, line 19: Examples I, IV, X-XII, XVI, XVII; claims 1-6). Various modes of administration are disclosed, including IV, oral, vaginal, rectal, depending on the condition being treated (column 9, lines 27-31). The anolyte, which contains ozone and active chlorine species such as hypochlorite (ClO^-), can have a pH of between about 7.2 and 7.6 (paragraph bridging columns 4 and 5). For an IV injection mode of administration, 0.25 to 4 ml/kg/day dose is disclosed (column 9, lines 31-34). Regimen may vary according to the indication being treated (column 9, lines 37-38). A "moderating" agent, which is a reducing agent (column 7, lines 29-30), is administered orally to prevent the free radical components of the electrolyzed saline from "causing irreparable tissue damage" (sentence bridging columns 9-10). Administration of moderating agent prior to, concurrently or after the administration of the anolyte is taught (column 5, lines 30-33). Oral dosage is higher than IV dosage (column 9, lines 54-56). The modulating agent

can be superoxide dismutase (column 10, line 3). Generally, superoxide dismutase amount of about 5,000 to 60,000 units per day may be administered (column 10, lines 11-13). Based on such guidelines, Morrow states that one skilled in the art "can readily determine what is an effective amount of modulating agent" (column 10, lines 23-25). Variations in voltage, amperage, volume and concentration of saline, electrodes are taught to affect the electrolysis reaction (column 8, lines 59, 67).

Shirahata et al. disclose reduced water near the cathode during electrolysis of water to have high pH and significant negative redox potential values, which reduced water inhibits DNA damage caused by oxygen radicals via antioxidant properties (see pages 269 & 273, right column). Higher pH, such pH 11, corresponds to more negative ORP, such as -800 mv (see first graph on page 270). The activity is disclosed as "superoxide dismutase (SOD)-like" (page 269, left column).

The article by Kroschwitz et al. is cited to establish that the electrochemical reactor features of the instant invention is conventional electrolysis technology, which would have been within the skill of the ordinary skilled artisan in this field (see pages 124-133, 135-140). Various oxychlorine species are disclosed upon electrolysis of a chloride solution (pages 133-135). Cells may be arranged in series or parallel circuits (page 125, bottom text part).

While the cited references do not expressly disclose in a single embodiment every single feature claimed by applicant, the combination of the references fairly suggests the claimed invention as a whole.

The primary reference, WO 99/20287, does not expressly provide for the following claim feature:

altering the chemical composition of the two solutions by one or more of various hydraulic flow arrangements, linking electrolytic cell modules in various configurations in order optimally to address the requirements of specific areas of application, and manipulating flow rate, hydraulic pressure, concentration, temperature, current density and/or voltage on the electrodes;

However, the fact that the two solutions are affected by the claimed parameters is but a truism. Hydraulic flow arrangements affect hydraulic flow, which affects the rate of flow, which affects electrolysis and the resultant solutions. Various configurations of electrolytic cells being linked affect the direction of flow and electrolysis effect. Flow rate, hydraulic pressure, concentration, temperature, current features all affect electrolysis, as disclosed or suggested by WO 99/20287, Morrow and Kroschwitz et al. Since the references teach monitoring various electrolysis parameters to produce the output solution (WO 99/20287, page 4, lines 5-7; Morrow, paragraph bridging columns 8-9), one having ordinary skill in the art would have been motivated to follow such

guidance to produce the prior art anolyte and catholyte; e.g. the anolyte and catholyte of WO 99/20287.

WO 99/20287 also does not expressly disclose simultaneous or sequential introduction of the cation-containing solution (catholyte) into the drinking water of the live animals. However, the combination of Morrow and Shirhata et al. amply suggest the same. Morrow specifically teaches orally administering a reducing agent such as superoxide dismutase before, concurrently or after administering the anolyte. Morrow administers the reducing agent so that the free radical components of the anolyte are inhibited from "causing irreparable tissue damage." Shirhata et al. disclose the use of SOD-like reduced water (i.e. catholyte) with alkaline pH and high negative ORP values to inhibit DNA damage caused by oxygen radicals via antioxidant properties (see pages 269 & 273, right column). The ordinary skilled artisan would have been motivated to utilize the catholyte of WO 99/20287 as the reducing agent to administer in conjunction with the anolyte of WO 99/20287, because the catholyte is conveniently produced along with the anolyte and the catholyte would have been expected to ameliorate the damaging effect of oxygen radicals present in anolyte, after it has performed the necessary microbicidal functions (see Morrow, column 10, lines 8-11).

While the catholyte being used directly as drinking water is not expressly disclosed by the references, the ordinary skilled artisan would have been motivated to

do so from the expectation that the catholyte directly provides antioxidant properties and inhibit DNA damage.

A dosage of 5-20 ml/kg, in particular 10 ml/kg, of the catholyte is not expressly disclosed by the references. However, Morrow exemplifies an IV injection dosage of 0.25 to 4 ml/kg/day (column 9, lines 31-34). Given such amount of the oxidizing solution (anolyte), taken with knowledge of needing higher dose when orally administered (Morrow, column 9, lines 54-55), one having ordinary skill in the art would have been motivated to arrive at a catholyte dosage, which acts to modulate the oxidizing activity to minimize cellular damage. This is particularly the case since the ordinary skilled artisan knows the oxidizing potential of the anolyte and has been provided with guidance of, for example, how much superoxide dismutase to use. As Morrow states, from such guidance and knowledge of reducing potential of the catholyte, the prior art fairly suggests an amount of superoxide dismutase-like catholyte, as claimed.

Lastly, claim 13 requires anolyte introduced into the drinking water of the animals at 15% by volume. WO 99/20287 exemplifies anolyte solution diluted to 10%. Further, WO 99/20287 discloses redox potential range of +600 to +800 mv and pH range of about 6.5 to 7.5. Therefore, adjustment to 15% dilution would have been obvious from the need to modify in accordance with severity of infection to be controlled and to account for differences in the output anolyte strength.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN PAK
PRIMARY EXAMINER
GROUP 1600

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